Application No.:

10/520,436

Filing Date:

August 17, 2006

AMENDMENTS TO THE CLAIMS

- 1. (Currently amended) A method for the separation and purification of fibrinogen and at least one other protein which comprises the steps of:
 - (a) loading a solution comprising fibrinogen and at least one other protein onto an <u>immobilized immobilised</u> metal ion affinity chromatography matrix under conditions such that the fibrinogen and the at least one other protein both bind to the matrix, and
 - (b) selectively eluting the fibrinogen and the at least one other protein separately from the matrix.
- 2. **(Previously presented)** The method according to claim 1 wherein the at least one other protein is plasminogen.
- 3. **(Currently amended)** A method for the separation of fibrinogen from plasminogen comprising the steps of:
 - (a) loading a solution comprising fibrinogen and plasminogen onto an <u>immobilized immobilised</u> metal ion affinity chromatography matrix under conditions such that at least the fibrinogen binds to the matrix, and
 - (b) selectively eluting the fibrinogen from the matrix.
- 4. **(Previously presented)** The method according to claim 3, wherein the plasminogen and the fibrinogen are selectively eluted separately from the matrix.
- 5. **(Previously presented)** The method according to claim 1 or 3, wherein the solution comprising fibrinogen is a fibrinogen-containing plasma fraction.
- 6. **(Previously presented)** The method according to claim 1 or 3, wherein the solution comprising fibrinogen further comprises factor XIII, and the factor XIII is co-eluted with the fibrinogen from the matrix.
- 7. **(Currently amended)** A method for the co-purification of fibrinogen and factor XIII which comprises the steps of:
 - (a) loading a solution comprising fibrinogen and factor XIII onto an <u>immobilized</u> immobilised metal ion affinity chromatography matrix under conditions such that the fibrinogen and the factor XIII both bind to the matrix, and
 - (b) selectively co-eluting the fibrinogen and the factor XIII from the matrix.

8.-10. (Canceled)

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11. (Previously presented) Fibrinogen prepared by a method according to any of claims 1, 3 or 7.

12.-15. (Canceled)

- 16. (Withdrawn- Currently amended) A <u>lyophilized lyophilised</u> fibrinogen formulation comprising fibrinogen of Claim 11, factor XIII, a carbohydrate, an amino acid, a salt, a buffer and a detergent, the formulation being capable of dissolution in water at ambient temperature in less than 15 minutes to give a fibrinogen solution.
- 17. **(Withdrawn)** The formulation according to claim 16, wherein the concentration of the fibringen solution is at least about 60 mg/ml.
- 18. (Withdrawn) The formulation according to claim 16, which is heat treated to inactivate viruses.
- 19. **(Withdrawn)** The formulation according to claim 16, which is free from antifibrinolytic agents.
- 20. (Withdrawn- Currently amended) The formulation according to claim 16, which is free from <u>stabilizing stabilizing</u> proteins such as albumin.
 - 21. (Canceled)

fibrinogen formulation;

- 22. (Withdrawn- Currently amended) The <u>lyophilized lyophilised</u> fibrinogen formulation of Claim 16, wherein the formulation being capable of dissolution in water at ambient temperature in less than 10 minutes to give a fibrinogen solution.
- 23. (Withdrawn- Currently amended) The <u>lyophilized lyophilised</u> fibrinogen formulation of Claim 16, wherein the formulation being capable of dissolution in water at ambient temperature in less than 5 minutes to give a fibrinogen solution.
- 24. (New) The method of Claim 1, 3 or 7 further comprising the step of concentrating the fibringen by ultrafiltration to a concentration of approximately 15 to 30 mg/ml.
 - 25. (New) The method of Claim 24 further comprising the steps of: combining the fibrinogen with a combination of suitable stabilizers to form a

sterilizing the fibrinogen formulation by filtration; and

lyophilizing the fibrinogen formulation to form a lyophilized fibrinogen formulation.

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26. (New) The method of Claim 25, wherein the stabilizers are selected from the group consisting of an amino acid, a carbohydrate, a salt, and a detergent.

27. (New) The method of Claim 25 further comprising the step of subjecting the lyophilized fibrinogen formulation to dry heat treatment.